

4. P03: Incidence Rates of Non-Neoplastic Lesions By Anatomic Site

Chapter 4

4.1 Overview

Pathology Report P03, *Incidence Rates of Non-Neoplastic Lesions By Anatomic Site*, summarizes non-neoplastic morphologies by treatment group. The first section of the report provides information on the male treatment groups, and the second section provides information on the female treatment groups. The tissues are listed alphabetically by system, and the corresponding observations are listed directly beneath that tissue. The observations are listed alphabetically by site (if entered) then morphology.

The P03 report can be customized by checking the “Extended Selections” feature on the TDMSE Reports, Request Reports menu screen. See Chapter 2: Request Reports, *TDMSE Reports User’s Guide* for more details.



All Extended Selections are available, except Control Group.

Each report contains:

- Strain, Species, Sex
- Treatment Group Description
- Disposition summary that includes the initial number of animals in study, early deaths, survivors, and animals examined microscopically, scheduled sacrifices, scheduled sacrifices without necropsy
- System(s) such as alimentary, cardiovascular, endocrine, general body, genital, hematopoietic, integumentary, musculoskeletal, nervous, respiratory, special senses and urinary
- Tissue(s), Tissue count
- Observation(s), Observation count, Observation percentage

4.2 P03 Incidence Rates of Non-Neoplastic Lesions by Anatomic Site(a) Description

TDMS No. 05042 - 01 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344/N		P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) tris(2-Chloroethyl) phosphate CAS Number: 115-96-8			Date Report Requested: 06/11/2009 Time Report Requested: 02:04:12 First Dose M/F: 09/07/82 / 09/07/82 Lab: MBA
Strain/Species & Sex	FISCHER 344 RATS MALE	CONTROL MALE	44MG/KG LOW MALE	88 MG/KG HIGH MALE	Treatment Group Description
Disposition Summary					
Disposition Summary includes: initial # of animals in study, # of early deaths, # survivors, # animals examined microscopically, scheduled sacrifices, SSAC w/o nec.	Animals Initially In Study	60	60	60	
	Early Deaths				
	Accident			1	
	Dead	6	9	10	
	Gavage Death	4	1		
	Interval Sacrifice	9	10	10	
	Moribund	5	7	14	
	Survivors				
	Terminal Sacrifice	36	33	25	
	Animals Examined Microscopically	50	50	50	
System	ALIMENTARY SYSTEM				
Tissue(s)	Esophagus	(50)	(48)	(50)	Tissue Count (in parentheses)
	Hemorrhage	1 (2%)	1 (2%)		
	Inflammation, Chronic	1 (2%)		1 (2%)	
	Inflammation, Chronic Active	1 (2%)			
	Wall, Foreign Body	1 (2%)			
	Intestine Large, Cecum	(50)	(47)	(48)	
	Hemorrhage			1 (2%)	
	Ulcer, Multifocal			1 (2%)	Observation Count
	Intestine Large, Colon	(50)	(47)	(49)	
	Inflammation, Subacute		1 (2%)		
	Intestine Small, Duodenum	(48)	(46)	(47)	
	Erosion		1 (2%)		
	Artery, Inflammation, Chronic	1 (2%)			
	Intestine Small, Ileum	(48)	(46)	(47)	
	Liver	(50)	(50)	(50)	
	Angiectasis	3 (6%)	1 (2%)	1 (2%)	
	Basophilic Focus	13 (26%)	6 (12%)	2 (4%)	
	Congestion	2 (4%)	1 (2%)	1 (2%)	
	Degeneration, Cystic		2 (4%)	1 (2%)	Observation % (in parentheses)
	Eosinophilic Focus		1 (2%)		
	Fatty Change, Focal	2 (4%)	1 (2%)	2 (4%)	
Footnote	a - Number of animals examined microscopically at site and number of animals with lesion				

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Figure 4-1: P03-Incidence Rates of Non-Neoplastic Lesions by Anatomic Site




Table 4-1 lists and describes the fields of the P03-Incidence Rates of Non-Neoplastic Lesions by Anatomic site.

Field	Description
Strain/Species/Sex	<ul style="list-style-type: none"> This field lists the strain, species and sex of animals for the identified experiment.
Treatment Group Description	<ul style="list-style-type: none"> This field identifies the treatment group and dose for the animals listed on this page. This field provides a description of the treatment administered to each group of animals as defined in the TDMSE Protocol application. The P03 report displays up to 6 treatment groups per page.
Disposition Summary	<ul style="list-style-type: none"> This field summarizes the animal disposition for this experiment. ANIMALS INITIALLY IN STUDY: The number of animals initially in the study. EARLY DEATHS: The number of animals that died before the end of the experiment. This category lists the reasons for early removal with the number of animals per treatment group (<i>See note after this table</i>). <ul style="list-style-type: none"> Removal Reasons: The rationale used for removing animals from the study. Removal reasons are listed in chronological order. SURVIVORS: The number of animals that survived the experiment (<i>See note following this table</i>). <ul style="list-style-type: none"> Removal Reasons: The rationale used for removing animals from the study. Removal reasons are listed in chronological order. ANIMALS EXAMINED MICROSCOPICALLY: The number of animals whose tissues were examined microscopically. SCHEDULED SACRIFICES: The number of animals sacrificed at a designated timepoint prior to the end of the study (not shown in this example). SSAC w/o NEC: The number of animals sacrificed at a designated timepoint prior to the end of the study and who will not undergo necropsy (Not shown in this example).
System(s)	<ul style="list-style-type: none"> This field lists the system(s) from the Pathology Code Table (PCT) studied for this experiment. Systems are listed in alphabetical order for each sex/species/treatment group combination. Each system is separated by a solid line.
Tissue(s)	<ul style="list-style-type: none"> This field lists the tissue(s) for the non-neoplasms observed. Tissues are listed alphabetically under each system.

Table 4-1: P03-Incidence Rates of Non-Neoplastic Lesions by Anatomic Site field descriptions

Field	Description
Tissue count	<ul style="list-style-type: none"> This field lists (in parentheses) the number of tissues examined. This includes both tissues with a status of normal and tissues with an observation, regardless of whether the observation is neoplastic or non-neoplastic.
Observation(s)	<ul style="list-style-type: none"> This field lists the observation(s) as recorded by the pathologist, in the following format: <ul style="list-style-type: none"> <i>Anatomical site</i> is specified if recorded. <i>Morphology</i> is always specified. <i>Qualifier</i> is specified if recorded. <i>Primary site</i> is specified if the tumor is metastatic. Sites are listed before an observation, if present. Multiple sites are listed alphabetically from left to right. Observation with single sites are listed before observations with multiple sites when the tissue and morphology are the same for both observations.
Observation count	<ul style="list-style-type: none"> This field lists the observation count for the number of animals with a specified observation. Identical observations for an animal/organ combination (those having the same morphology, sites, and qualifiers) are counted only once. Fields will be blank if no observation for a particular treatment group are noted.
Observation percentage	<ul style="list-style-type: none"> This field lists the observation percentage in parenthesis next to the observation count. The observation percentage is calculated by dividing the observation count by the tissue count multiplied by 100.
Footnote	<ul style="list-style-type: none"> a = The number of animals examined microscopically at site and the number of animals with lesions

Table 4-1: P03-Incidence Rates of Non-Neoplastic Lesions by Anatomic Site field descriptions

	<p>Early Deaths are counted as animals that were removed before the day of the first terminal sacrifice (TSAC).</p> <p>Survivors are counted as animals that are removed on/after the day of the first TSAC without regard to time of day.</p> <p>Example: A study exists with only four animals. Animal #1 is removed from a study at 9am on August 9th as a Natural Death. Animal #2 is removed from a study at 9am on August 10th as a Natural Death. Scheduled sacrifices begin later in the day. Animal #3 is removed from a study at 11am on August 10th as a TSAC. Animal #4 is found dead at 11:30 am on August 10th and is recorded as a natural death. The reports should count animal #1 as an early death. The reports should count animals #2, #3, #4 as survivors.</p>
	<p>The report is divided between males and females. The male report is presented first if data exists. An ‘***END OF REPORT***’ message will be displayed on the last page of the report.</p>
	<p>If no data are present the report generates a splash page as well as pages containing all row and column headers followed by ‘***END OF REPORT***’.</p>